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Medi-Globe/GIP Stone Extractor Balloon Catheters

Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The Medi-Globe/GIP Stone Extractor Balloon Catheters are similar in design, material composition, function and performance and intended use to the Wilson-Cook and Microvasive balloon catheters.

The Medi-Globe/GIP Stone Extractor Balloon Catheters are intended for endoscopic removal of biliary stones and for injection of contrast medium while occluding the common bile duct with the inflated balloon. The Medi-Globe/GIP Stone Extractor Balloon Catheters are designed for use in conjunction with various FDA approved duodenoscopes.

A comparison of the Medi-Globe/GIP Stone Extractor Balloon Catheters with referenced competitor balloons is outlined in Section 8. The method of operation is exactly the same when used in conjunction with the FDA registered endoscopes and components.

The Stone Extractor Balloon Catheters manufactured by Medi-Globe/GIP, as well as the predicate devices, are packaged individually and sterile, in peel-open pouches for single patient use.

Biocompatibility testing conducted through an independent laboratory indicates that the Medi-Globe Stone Extractor Balloon is safe for the labeled indications. The biocompatiblity data is found in Section 1-3 of the additionally submitted information.

All materials used to the Stone Extractor Balloon Catheters are similar in specification and design to the predicate Stone Extractor Balloon Catheters and other FDA registered devices.

A detailed listing of sizes and lengths of Medi-Globe/GIP's Stone Extractor Balloon Catheters is included in Section 11, Exhibit C. The working lengths of the Stone Extractor Balloon Catheters are 200 *cm's* with diameters of 7 Fr. or *5* Fr.. The sizes and physical characteristics of the predicate devices are identical to those of Medi-Globe/GIP.

The Medi-Globe/GIP manufacturing facility has been awarded the TUV Award for Good Manufacturing Practices (GMP), maintains CE Mark/EC Certification and operates in accordance with ISO 9001.

Medi-Globe/GIP Stone Extractor Balloon Catheters

In summary, the Medi-Globe/GIP Stone Extractor Balloon Catheters are safe and effective when used in accordance with their intended use and enclosed instruction manual.

For any questions regarding the Medi-Globe/GIP Stone Extractor Balloon Catheters, please contact Gerhardt Seiwerth or Scott Karler (information see below).

CONTACT INFORMATION:

U.S. Headquarters	German Manufacturer
Medi-Globe Corporation 6202 S. Maple Ave., #131 Tempe, Arizona 85283 USA	Medi-Globe GmbH Medi-Globe Strasse 1-5 D-83101 Achenmule, Germany
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2003

Mr. Scott Karler
Marketing Coordinator
Medi-Globe Corporation
6202 S. Maple Avenue, #131
TEMPE AZ 85283

Re: K011261
Trade/Device Name: Medi-Globe/GIP Stone Extractor Balloon Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: August 18, 2003
Received: August 19, 2003

Dear Mr. Karler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: K011261

DEVICE NAME: Medi-Globe/GIP Stone Extractor Balloon Catheter

INDICATIONS FOR USE

Stone Extractor Balloon Catheters manufactured by Medi-Globe/GIP are intended for endoscopic removal of biliary stones and for injection of contrast medium while occluding the common bile duct with the inflated balloon.

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011261

Prescription Use ✓
(Per 21 CFR 801.109)